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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/467,100	12/10/99	COLEMAN R	PF-0049-2-DI

HM12/0828

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PATENT DEPARTMENT
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EXAMINER	
HUTSON, R	
ART UNIT	**PAPER NUMBER**
1652	12

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/467,100	COLEMAN ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-42* is/are pending in the application.

4a) Of the above claim(s) *41 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants amendment of the specification, cancellation of claims 5 and 14-29 and addition of new claims 30-42 is acknowledged. Claims 30-42 are at issue and are present for examination.

Applicants' arguments filed on 6/18/2001, paper No. 11, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Newly submitted claims 41 and 42 are directed to an invention that is independent or distinct from the invention originally elected. Claim 41 should be grouped with group VII of the restriction requirement in Paper No. 5, filed 5/3/2000. Claim 42 is patentably distinct from the elected subject matter because the claim is drawn to a method of assessing the toxicity of a test compound, which is related to the claimed subject matter as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid product can be used in different process such as the recombination of the encoded polypeptide.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41 and 42 are withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 (37-40 dependent from) is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising a polynucleotide sequence of SEQ ID NO: 1, or a polynucleotide sequence having at least 92% sequence identity to the polynucleotide sequence of SEQ ID NO: 1, wherein said polynucleotide encodes a polypeptide which has kinase activity, does not reasonably provide enablement for any isolated polynucleotide comprising a polynucleotide sequence having greater than 92 % sequence identity to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A similar rejection as above was stated in the earlier office action, Paper No. 7, 9/1/2000, and argued in the response to that action, Paper No. 9, 12/27/2000, as it applied to claim 19. As was stated in the previous office actions, applicants argue on two different basis, "How to use" and "How to make".

Applicants are persuasive in there "How to Make" argument.

With respect to "How to use" applicants argued that the scope of the claim (19) was fully enabled by the specification. As previously stated with respect to earlier claim 19, the recitation in claim 36, b), "a naturally occurring amino acid sequence having at least 92% sequence identity to the polynucleotide sequence of SEQ ID NO: 1 " encompasses polynucleotide variants encoding naturally occurring orthologs in related species, particularly human polypeptide variants with mutations that result in altered activity. It is unclear what function a polypeptide variant with a mutation that results in "altered activity" has and absent a teaching of this "specific altered activity", how the polynucleotides which encode these polypeptides are enabled with respect to there use.

Claim 36 (37-40 dependent from) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A similar rejection as above was stated in the earlier office action, Paper No. 7, 9/1/2000, and argued in the response to that action, Paper No. 9, 12/27/2000, as it applied to claim 19.

Applicants traversed this rejection on the basis that it was made for "naturally occurring sequence" and "fragments" separately.

As was previously stated, applicants amendment and argument with respect to claim 19 c) drawn to those recombinant polynucleotides comprising a promoter

sequence operably linked to a polynucleotide encoding a polypeptide comprising a fragment of an amino acid sequence of SEQ ID NO: 2, wherein said fragment has kinase activity, applicants argument was persuasive.

With respect to earlier claim 19 b) and now claim 36 b), naturally-occurring sequence, applicants argue that the subject matter encompassed by the claims is either disclosed by the specification or is conventional or well known to one of ordinary skill in the art as the specification teaches the polypeptide of SEQ ID NO: 2, the specification describes where to find the claimed variants, gives the scope of the claims and tells how one can determine whether a given polypeptide sequence falls within the scope of the claims. Applicants further assert that the specification teaches how to find polynucleotide variants which can be used to make polypeptide variants and therefore the distinguishing attributes of the naturally occurring polypeptides having at least 92% identity to the sequence of SEQ ID NO: 1 (or 2) are fully described. However, it should be noted that the claimed genus of polypeptides of Claim 36, part b) are not fully described by the specification as each of this claimed genus includes polynucleotides of a wide diversity of functions. This much larger genus of polynucleotides includes species with a wide variety of functions and thus is not fully described by the specification. Furthermore, part b) recites a genus comprising all naturally-occurring polynucleotide sequences having 92% sequence identity to the sequence of SEQ ID NO: 1. This genus is at least so broad as to encompass all allelic variants of the polypeptide of SEQ ID NO: 1 (and might include all allelic variants of other genes if there are multiple highly homologous loci). Therefore, one skilled in the art cannot

reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation in newly added claim 36 (37-40 dependent from) of "92% identity" is rejected as being new matter that is not supported by the original specification. Applicants submission that the specification at page 3, lines 31-34 and page 7, lines 20-26 indicates that applicants envisioned Jak2 kinase variants of greater than 92% sequence identity to murine Jak2 kinase is not persuasive. It is acknowledged that at page 7, applicants envision a "recombinant polypeptide variant" and at page 3, applicants recognize that "HJAK2 has 92% similarity to murine Jak2" but applicants suggestion that "applicants envisioned Jak2 kinase variants of greater than 92%" is not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvennoinen et al.

As discussed in the previous office action with respect to claims 23-25 and 27-29, Silvennoinen et al. teach the structure of the murine Jak2 protein-tyrosine kinase, its role in interleukin 3 signal transduction and the cloning of a full-length cDNA clone for murine Jak1 and Jak2 protein-tyrosine kinase. A comparison of the amino acid sequence of the murine Jak2 protein shows that its best local similarity is 93.3% with that of SEQ ID NO: 2. Relative to SEQ ID NO: 1, the cDNA taught by Silvennoinen et al. has greater than 88 % best local similarity.

One of ordinary skill in the art at the time of filing would have been motivated to use the sequence taught by Silvennoinen et al. to design oligomers for use as primers to amplify and determine the level of mRNA encoding the murine Jak2 protein or to isolate other mRNAs encoding related proteins such as human Jak2 using hybridization or polymerase chain reaction methodology. As discussed above and in the previous office action, and seen in the comparison of the sequence of SEQ ID NO: 1 with the murine Jak2 cDNA, there exists many regions of identity between the two cDNAs. It is noted that it is a common practice in the art to design oligomers such that they do not correspond exactly to the sequence on which they are based. For instance often they are degenerate in order to identify additional members of a family and they incorporate additional bases for cloning, etc. Thus an oligomer of the polynucleotide comprising the nucleic acid sequence of SEQ ID NO: 1 is made obvious by Silvennoinen et al. Further, one of ordinary skill in the art would have been motivated to use these oligomers as part of a method for detecting the level of murine and human Jak2 mRNAs in tissue samples or identifying additional related mRNAs. Further motivation for the design and use of

oligomers based on murine Jak2 is that Silvennoinen et al. teach that the Jak2 protein is regulated in response to IL-3 and is involved in signal transduction associated with hematopoiesis and there interest in the role of Jak1 and Jak2 genes in IL-3 signal transduction.

Applicants traverse this rejection as it applied to claims claims 23-25 and 27-29, on the basis that the novel target polynucleotide recited by the claims is not disclosed by Silvennoinen et al. and without the coding information provided by the target sequence, Silvennoinen et al. could not have guided one of skill in the art on how to detect the target sequence. This argument is not found persuasive, because the specific sequence disclosed by the instant specification as SEQ ID NO: 1 is not necessary for motivation nor guidance to the claimed method. The claimed method is encompassed by the methods made obvious by Silvennoinen et al. discussed above. As discussed above and in the previous office action, and seen in the comparison of the sequence of SEQ ID NO: 1 with the murine Jak2 cDNA disclosed by Silvennoinen et al., there exists many regions of identity between the two cDNAs. It is noted that it is a common practice in the art to design oligomers such that they do not correspond exactly to the sequence on which they are based. For instance often they are degenerate in order to identify additional members of a family and they incorporate additional bases for cloning, etc. Thus an oligomer of the polynucleotide comprising the nucleic acid sequence of SEQ ID NO: 1 is made obvious by Silvennoinen et al., as are methods of using said oligomers for detecting target polynucleotides.

Thus claims 37-40 are made obvious by Silvennoinen et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-36 are rejected under the judicially created doctrine of double patenting over claims 1-3 of U. S. Patent No. 5,914,393 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A purified polynucleotide consisting of a nucleic acid sequence encoding the polypeptide of SEQ ID NO: 2.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Applicants request that this rejection be held in abeyance until which time there is an indication of allowable subject matter is acknowledged.

Claims 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U. S. Patent No. 5,914,393 . Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of detecting a polynucleotide comprising a sequence of SEQ ID NO: 1 or variants thereof (claims 37-40) is obvious over claims to the polynucleotide consisting of SEQ ID NO: 1 or the complement thereof (claims 1-3). Claims 37-40, drawn to methods of detecting a polynucleotide comprising a sequence of SEQ ID NO: 1 or variants thereof are obvious over claims to the polynucleotide consisting of SEQ ID NO: 1 or the complement thereof (claims 1-3), because one of ordinary skill in the art would be motivated to design PCR and hybridization probes based on the sequence of SEQ ID NO: 1 for use in methods of detecting the presence and level of polynucleotides encompassed by and related to SEQ ID NO: 1. The motivation for such methods is they would be useful for the characterization of these nucleic acid sequences and the role they play in natural physiology and/or disease such that this information could be used to treat or enhance these conditions.

Applicants request that this rejection be held in abeyance until which time there is an indication of allowable subject matter is acknowledged.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson
August 24, 2001

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600